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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/028,258	12/19/2001	Celal Albayrak	0081.02	2329

21968 7590 11/17/2005

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EXAMINER	
WANG, SHENGJUN	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 11/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/028,258	ALBAYRAK, CELAL	
	Examiner	Art Unit	
	Shengjun Wang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 8-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 8-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt of applicants' amendments and remarks submitted August 22, 2005 is acknowledged.

Specification Objections

1. The use of the trademarks such as Poloxamere, Poloxamine , and Resomer etc. (page 18 and examples) has been noted in this application. ***It should be capitalized wherever it appears and be accompanied by the generic terminology.***

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

2. The disclosure is objected to because of the following informalities: page 13, line 6 "within the rage of 0 - ¯15" appears to be "within the range of 0 to –15."

Appropriate correction is required.

Double Patenting Rejections

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4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned

with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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1. Claims 1-6, 8-17, 20-30 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-41 of U.S. Patent No. 6,899,898. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed scope herein substantially overlaps with those in '898. '898 claims a process essentially the same as herein claimed except that non-water soluble active ingredients in '898 and hydrophilic active in the pending claims. Note that not all water-insoluble actives are hydrophobic, and not all hydrophilic actives are water-soluble.

Claim Rejections 35 U.S.C. 112

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2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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3. Claims 4, 14 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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4. Claim 4 recite "at least 1.5-40%" the claim is indefinite as to the range herein defined. E.g., it is not clear if 41% will meet the limitation herein required.

8
5. Claim 14 recites "the drug solution" There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections 35 U.S.C. 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 1-6, 8-17, 20-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rossling et al. (WO 97/19676).

11. The instant invention is directed toward a process of making microparticles comprising dissolving a polymer in a halogen free solvent that partially water miscible, adding a hydrophilic active agent, mixing the two, and adding an aqueous surfactant and mixing.

12. Rossling et al. teach a method of producing morphologically uniform microcapsules. The method comprising dissolving biodegradable polymers in a halogen-free solvent or solvent mixture, and then dispersing into this solution, a buffered, hydrophilic active ingredient solution. Then, an aqueous solution that contains a surface-active substance is added to the emulsion, and the solvent is removed by vacuum. The microcapsules are taught as ranging in size from 200nm to 500um. Polyglycolides, such as glycolide/lactide copolymers are taught as polymers. Acetone, ethanol, alkyl acetates, alkyl formats, triacetin, triethyl citrate, and/or alkyl lactates are taught as solvents. Tristhydroxmethyllaminomethane and citrate are taught as buffer solutions. Nonionic surfactants, polyethylene glycol, and others are taught as surfactants. The reference does not teach expressly the solubility parameters of the polymer solvent and the aqueous phase as less than zero and does not teach the preferred ratios of the polymer phase to the surfactant phase,

And the volume fraction of the surfactant phase. US 6,294,204 relied upon as an English translation, and see particularly column 1-5 therein. Applicants' attention is also directed to the claims (pages 20-22) in WO97/19676, wherein no particular ratio of the polymer phase and surfactant phase is required.

13. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the solubility parameters, ratios, and volumes of the polymer solvent and the aqueous phase of Rossling et al. because it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. Thus, one of skill in the art would be motivated to vary these parameters because of the expectation of achieving the most stable product, wherein the active ingredient is most efficiently and effectively delivered.

14. The Examiner respectfully point out instant claim 30 is a product-by-process claim. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). See MPEP 2113. However, since claim 30 depends on claims 1, 5, 8, 24 or 26, claim 30 is not being rejected under 102(b), though such microparticles are known in the art. Further note, there is no indication or requirement in WO97/19676 that require the formation of W/O/W emulsion.

15 Claims 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rossling et al. as applied to claims 1-17 and 20-30 above, and further in view of Setterstrom et al. (6,410,056).

Rossling et al. is applied as discussed above. The reference lacks microspheres and microsponges.

Setterstrom et al. teach that microspheres tend to be more difficult to rupture as compared to microcapsules because of their internal structure is stronger. Microsponges are taught as porous microspheres. See Col. 3, lines 44-56.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the microparticles of Rossling et al. into microspheres instead of microcapsules because of the expectation of achieving a formulation that is stronger and does not rupture as easily, thereby producing a formulation that is longer-lasting once ingested.

Response to the Arguments

Applicants' amendments and remarks submitted August 22, 2005 have been fully considered, but are not persuasive as to the pending claims.

16 In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., forming a suspension of the microparticles immediately after the adding the surfactant phase to the drug phase) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

9. Following limitation to claim 1 would be favorably considered: "wherein a suspension of the polymeric microparticles is formed within one minute of mixing the surfactant phase with the drug phase." See page 13, lines 13-15 of the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SHENGJUN WANG
PRIMARY EXAMINER

Shengjun Wang
Primary Examiner
Art Unit 1617